

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X

IN RE: ORAL PHENYLEPHRINE MARKETING :
AND SALES PRACTICES LITIGATION :
: 23-md-3089-BMC

THIS DOCUMENT APPLIES TO:

ALL CASES

X

CASE MANAGEMENT ORDER NO. 2

QUALIFIED PROTECTIVE ORDER AND AGREED CONFIDENTIALITY ORDER

I. SCOPE OF PROTECTIVE ORDER

A. Purpose

The Parties anticipate that documents, testimony, or information that contain or reflect confidential, proprietary, trade secret, and/or commercially sensitive information could be requested, disclosed, or produced during the course of discovery, initial disclosures, and/or supplemental disclosures in this Litigation. Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and 45 C.F.R. § 164.512(e)(1), the Court finds good cause for the issuance of a qualified protective order governing confidentiality.

B. Applicability

The Parties acknowledge that this Protective Order governs discovery in *In re: Oral Phenylephrine Marketing and Sales Practices Litigation* (MDL No. 3089), Case No. 23-md-3089.

This Protective Order shall apply to all actions currently pending in MDL No. 3089, including any appeal therefrom, and to all related actions that have been or will be originally filed in, transferred to, or removed to this Court and assigned hereto.

In the event of transfer of these actions to other courts, this Protective Order will remain in effect in all respects, until adopted by the transferee court or replaced by a successor order. The terms and specifications of this Protective Order shall only apply to document productions made after the date of entry of this Protective Order. To the extent additional obligations or rights not addressed in this Protective Order arise under the Federal Rules, Local Rules, or other applicable state and federal statutes, they shall be controlling.

The entry of this Protective Order does not prevent any Party from seeking a further order of this Court pursuant to Federal Rules of Civil Procedure 26(c) or 37(a). Nothing in this Protective Order shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence and/or preclude any Producing Party from using its own Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information in any manner it sees fit, without prior consent of any Party or the Court.

II. General

1. Application of Protective Order

Disclosure and discovery activity in this action could involve requests for and production of certain confidential, proprietary, or private information, provided from this or related litigation(s), for which special protection from public disclosure and from use for any purpose other than prosecuting this Litigation may be warranted. Accordingly, the Parties hereby stipulate to and petition the Court to enter this Protective Order.

All materials produced or adduced in the course of discovery, including initial disclosures, responses to discovery requests, deposition testimony and exhibits, and information derived directly therefrom (hereinafter collectively “documents”), shall be subject to this Protective Order as defined below. This Protective Order is subject to the Federal Rules of Civil Procedure, the Local Rules of the Eastern District of New York, and the Individual Practices of Judge Brian M. Cogan on matters of procedure and calculation of time periods.

2. Binding on Parties

This Protective Order is binding on all Parties and their counsel in all cases currently pending or subsequently made part of these MDL proceedings and shall govern each case in the proceedings. The purpose of this Protective Order is to expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, and protect material to be kept confidential, pursuant to the Court’s inherent authority, its authority under Federal Rule of Civil Procedure 26(c) and Federal Rule of Evidence 502(d), and the judicial opinions interpreting such Rules.

3. No Blanket Protections

The Parties also acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords from public disclosure and use extends only to the information or items that are entitled to confidential treatment under the applicable legal principles.

4. No Limitations of Other Rights; Jurisdiction

This Protective Order shall not abrogate or diminish any contractual, statutory, or other legal obligation or right of any party or person with respect to any Confidential Information. Nothing herein shall be construed as an admission or concession by any Party that designated

Confidential Discovery Material, or any Document or Information derived from Confidential Material, was appropriately designated as Confidential Material or constitutes material, relevant or admissible evidence in this Litigation.

The recipient of any Confidential Information hereby agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings related to the performance under, compliance with, or violations of this Protective Order.

5. Definitions

- a) This "Litigation," as used herein, means MDL No. 3089, any actions remanded therefrom, and any appeals thereof.
- b) The "Protective Order," as used herein, means this Qualified Protective Order and Agreed Confidentiality Order, as filed.
- c) "Producing Party," as used herein, means any Party to this Litigation or any Non-Party who produces, provides, and/or designates materials or testimony containing Confidential Information, Highly Confidential Information, and/or Outside Attorneys' Eyes Only Information.
- d) "Receiving Party," as used herein, means any Party to the Litigation or any Non-Party to whom a Producing Party produces materials or testimony containing Confidential Information, Highly Confidential Information, and/or Outside Attorneys' Eyes Only Information.
- e) "Third Party," as used herein, covered by this Protective Order is intended to include third parties who respond to discovery requests and/or subpoenas initiated by the Parties or the Court.
- f) "Document," as used herein shall be accorded its broadest possible meaning as defined by Local Rule 26.3(c)(2) in the Local Rules for the Southern and Eastern District of New York,

and shall include, without limitation, the whole page or file or any portion thereof of any written, printed, or graphic matter, and any computer file, record, or tape produced by or obtained from any Party or Non-Party, any electronically stored information, or any copy, extract, or complete or partial summary prepared therefrom, and any document or thing covered by Fed. R. Civ. P. 34.

g) “Confidential Information,” as used herein, means information of any type, kind, or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains: (1) information that the Producing Party reasonably believes constitutes a trade secret under applicable statutory and case law; or (2) information that the Producing Party reasonably believes constitutes such highly sensitive technical or proprietary business information of such Producing Party that its disclosure might result in an unfair competitive, financial, or commercial advantage to the Receiving Party or competitors or disadvantage to the Producing Party; or (3) Protected Health Information, as defined herein; or (4) personal identifying information, personal data, sensitive personal data, or other data a party believes in good faith to be subject to federal, state, or foreign data protection laws; or (5) any other sensitive information or tangible things (regardless of how they are generated, stored or maintained) that requires protection under Federal Rule of Civil Procedure 26(c).

h) “Highly Confidential Information,” as used herein, means Confidential Information that the Producing Party believes in good faith would, if disclosed, including to non-attorney employees, contractors, or consultants of Parties to this Litigation, cause a substantial risk of a significant competitive or commercial disadvantage to the Producing Party, including but not limited to information that reflects: the Producing Party’s competitiveness in the market; sales or marketing strategies; research and development materials; or non-public dealings with or

internal deliberations concerning any regulatory body such as the FDA or other authority.

- i) “Outside Counsel’s Eyes Only Information,” as used herein, means Highly Confidential Information designated as such by the Producing Party, which includes business strategies, trade secrets, financial information, research and development materials, or other sensitive scientific or business information that a Producing Party considers in good faith to contain information, the disclosure of which not only to the public and employees, contractors, or consultants of a Party to this Litigation, but also to in-house counsel of a Party to this Litigation, would create a substantial risk of serious competitive, business, or financial harm.
- j) “Personal Data,” as used herein, shall mean any information relating to an identified or identifiable natural person subject to protection under state, federal, or foreign data protection or privacy law (including but not limited to the Health Insurance Portability and Accountability Act (“HIPAA”) and the EU’s General Data Protection Regulations. For purposes of this Protective Order, an identifiable natural person is one who can be identified, directly or indirectly, in particular by referencing an identifier such as, but not limited to, a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person.
- k) “Protected Health Information,” as used herein, shall have the same definition as set forth in [45 CFR § 160.103](#).
- l) “Competitor,” as used herein, means, with regard to any Defendant, any current manufacturer or seller of phenylephrine-containing products other than the Producing Party, which may include, but is not limited to, other Defendants in this Litigation. It also includes any other market participant in a market in which a Defendant participates (either directly or indirectly).

III. SCOPE OF CONFIDENTIALITY

A. Protected Information

As used in this Protective Order, the Parties will be able to designate confidential, proprietary, and/or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this Litigation would be warranted under the following three designations: “Confidential Information,” “Highly Confidential Attorneys’ Eyes Only Information,” and “Outside Counsel’s Eyes Only Information.” The Parties anticipate that documents will be reviewed for applicability of these categories and, in recognition of such, the Parties will make a good faith effort to make reasonable and proportionate use of the confidentiality designations.

1. Confidential

As used in this Protective Order, “Confidential Information” means information designated as “CONFIDENTIAL” by the Producing Party that falls within one or more of the following categories: (a) information prohibited from disclosure by law, statute, or regulation, including but not limited to protected health information contained in clinical trial data, study data, and/or internal company records; (b) proprietary research, technical, commercial, or financial information that the party has maintained as confidential and as to which disclosure might result in unfair competitive, financial, or commercial advantage to the Receiving Party or Competitors or disadvantage to the Producing Party; (c) personal identity information, which may be subject to federal and foreign protection regulations; (d) income tax returns (including attached schedules and forms), W-2 forms, and 1099 forms; (e) personnel or employment records of a person who is not a Party to the case; or (f) any other sensitive information or tangible things (regardless of how

they are generated, stored or maintained) that require protection under Federal Rule of Civil Procedure 26(c).

“Confidential Information” can apply to information contained within a document, revealed during a deposition or other testimony, revealed in a written discovery response, or otherwise revealed. The Parties anticipate that documents will be reviewed by the Producing Party for applicability of these categories and, in recognition of such, the Producing Party will make a good faith effort to make reasonable and proportionate use of the confidentiality designations.

2. Highly Confidential – Attorney’s Eyes Only

As used in this Protective Order, “Highly Confidential – Attorneys’ Eyes Only Information” means information which if disclosed, disseminated, or used by or to a Competitor of the Producing Party or any other person not otherwise enumerated herein could reasonably result in possible antitrust violations, disclosure of trade secrets, or commercial or financial and/or information that creates an extraordinary risk of harm, including harm to Non-Parties. This includes Protected Health information and other extremely sensitive Confidential information, disclosure of which to another Party or Non-Party would create a substantial risk of serious harm that could not be avoided by less restrictive means, including but not limited to documents where disclosure may cause competitive injury, and/or Personal Data as defined herein.

This Protective Order is HIPAA-compliant pursuant to 45 C.F.R. § 164.512 (e)(1)(v). The Parties agree that a Receiving Party (or any other person who receives Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information from a Receiving Party) may use Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information only for the purposes of the Litigation, including documents that contain Protected Health Information and individually identifiable health

information that is protected from unauthorized disclosure by HIPAA, codified in 45 C.F.R. §§ 160, 164. The Receiving Party must return or destroy all documents containing Protected Health Information to the Producing Party (including all copies made) at the end of the Litigation pursuant to the final disposition provision, included in Section K of this Protective Order.

3. Highly Confidential – Outside Counsel Only

As used in this Protective Order, “Outside Counsel’s Eyes Only Information,” means information that may be shared only with (i) Plaintiffs’ attorneys of record in the Litigation, including clerical, secretarial, and other staff employed or retained by Plaintiffs’ counsel, (ii) outside counsel for a Party, including counsel’s clerical, secretarial, and other staff employed or retained by such counsel, and (iii) persons otherwise specifically enumerated by the Parties, including but not limited to insurers, auditors, vendors, and experts. This information may be disclosed to outside counsel for the Parties but is restricted from disclosure, dissemination, or use by Party attorneys not otherwise involved in this Litigation.

4. Designation

A Party may designate a document as Confidential Information for protection under this Protective Order by placing or affixing the words “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or “OUTSIDE COUNSEL EYES ONLY” on the document and on all copies in a manner that will not interfere with the legibility of the document. As used in this Protective Order, “copies” includes electronic images, duplicates, extracts, summaries, or descriptions that contain the Confidential Information. The marking “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or “OUTSIDE COUNSEL EYES ONLY” shall be applied prior to or at the time the documents are produced or disclosed. Applying the marking “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL

– ATTORNEYS’ EYES ONLY,” or “OUTSIDE COUNSEL EYES ONLY” to a document does not mean that the document has any status or protection by statute or otherwise except to the extent and for the purposes of this Protective Order. Any copies that are made of any documents marked “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or “OUTSIDE COUNSEL EYES ONLY” shall also be so marked, except that indices, electronic databases, or lists of documents that do not contain substantial portions or images of the text of marked documents and do not otherwise disclose the substance of the Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information are not required to be marked.

The designation of a document as Confidential, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel Eyes Only, constitutes a certification by the Producing Party that one or more individual attorneys have reviewed that particular document and that a specific and reasoned determination has been made, in good faith and consistent with the professional judgment of that attorney or those attorneys, that the document contains information that meets the definitions of Confidential, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel Eyes Only, as such definitions are set forth in this order.

B. Depositions

All deposition testimony shall initially be treated as Outside Counsel’s Eyes Only Information protected by this Protective Order until thirty days after delivery of the final transcript by the court reporter to any Party or the witness. Within thirty days after delivery of the final transcript, a Producing Party may serve a Notice of Designation to all parties of record identifying the portions of the transcript that are designated Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information, and thereafter those portions

identified in the Notice of Designation shall be protected under the terms of this Protective Order. The failure to serve a timely Notice of Designation waives any designation of deposition testimony as Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information, unless otherwise ordered by the Court.

In the event that In-House Counsel (or current employees) of any Competitor, who is a party to this Litigation, of the Producing Party is present at the deposition of any employee or former employee of the Producing Party, prior to a document designated as Highly Confidential – Attorneys’ Eyes Only Information or Outside Counsel’s Eyes Only Information being used in an examination, such In-House Counsel (or current employees) of any competitor, who is a Party to this Litigation, of the Producing Party shall excuse himself or herself from the deposition room without delaying or disrupting the proceedings.

C. Protections of Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information

1. General Protections

Confidential Information shall not be used or disclosed by the Parties, counsel for the Parties or any other persons identified in subparagraph (2) for any purpose whatsoever other than in this Litigation, including any appeal thereof. Confidential Information may be disclosed only to the named plaintiff(s) and not to any other member of the putative class absent further order of the Court.

2. Limited Disclosure for Confidential Information

The Parties and counsel for the Parties shall not disclose or permit the disclosure of any Confidential Information to any third person or entity except as set forth in subparagraphs (1)-(9). Subject to these requirements, the following categories of persons may be allowed to review

Confidential Information:

- (1) Counsel. Outside Counsel and In-House Counsel for the Parties and employees of counsel who have responsibility for the action;
- (2) Parties. Individual Parties and employees of a Party but only to the extent counsel determines in good faith that the employee's assistance is reasonably necessary to the conduct of the litigation in which the information is disclosed;
- (3) Mediators, the Court and their personnel;
- (4) Court Reporters and Recorders. Court reporters and recorders engaged for depositions;
- (5) Contractors. Those persons specifically engaged for the limited purpose of making copies of documents or organizing or processing documents, including outside vendors hired to process electronically stored documents;
- (6) Consultants and Experts. Consultants, investigators, or experts employed by the Parties or counsel for the Parties to assist in the preparation and trial of this action but only after such persons have completed the certification contained in Attachment A;
- (7) Witnesses at depositions. During their depositions, witnesses in this action to whom disclosure is reasonably necessary. Witnesses shall not retain a copy of documents containing Confidential Information, except witnesses may receive a copy of all exhibits marked at their depositions in connection with review of the transcripts. Pages of transcribed deposition testimony or exhibits to depositions that are designated as Confidential Information pursuant to the process set out in this Protective Order must be separately bound by the court reporter and may not be disclosed to anyone except as permitted under this Protective Order;
- (8) Author or recipient. The author or recipient of the document (not including a person who received the document in the course of litigation); and
- (9) Others by Consent. Other persons only by written consent of the Producing Party or upon order of the Court and on such conditions as may be agreed or ordered.

3. Limited Disclosure for Highly Confidential – Attorneys’ Eyes Only Information

The Parties and counsel for the Parties shall not disclose or permit the disclosure of any Highly Confidential – Attorneys’ Eyes Only Information to any third person or entity except as set forth in subparagraphs (1)-(9). Subject to these requirements, the following categories of persons may be allowed to review Highly Confidential – Attorneys’ Eyes Only Information:

- (1) Outside Counsel and In-House Counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel: provided, however, that information designated as Highly Confidential–Attorneys’ Eyes Only Information by any Defendant may be disclosed to In-House Counsel of another Defendant only if (i) that In-House Counsel has regular involvement with the Litigation; (ii) disclosure to that In-House Counsel is reasonably necessary to this Litigation; and (iii) that In-House Counsel completes the certification contained in Attachment A;
- (2) Except as otherwise provided in this Protective Order or any other order in this Litigation, no other employees of any Defendant may receive the Highly Confidential – Attorneys’ Eyes Only Information of another, or be shown such material at a deposition;
- (3) Mediators, the Court and their personnel;
- (4) Court Reporters and Recorders. Court reporters and recorders engaged for depositions;
- (5) Contractors. Those persons specifically engaged for the limited purpose of making copies of documents or organizing or processing documents, including outside vendors hired to process electronically stored documents, provided that the contractor agrees to be bound by this Protective Order and completes the certification contained in Attachment A;
- (6) Consultants and Experts. Consultants, investigators, or experts employed by the Parties or counsel for the Parties to assist in the preparation and trial of this action but only after such persons have completed the certification in Attachment A;
- (7) Witnesses during deposition who may be shown, but shall not be permitted to retain, Highly Confidential – Attorneys’ Eyes Only

Information; provided, however, that, unless otherwise agreed by the relevant Parties (whether prior to or at the deposition) or order by the Court, no Highly Confidential – Attorneys’ Eyes Only Information of a Defendant may be shown to any witness who is a current employee of another Defendant or is not otherwise authorized to receive the information under this Protective Order.¹ In the event that a testifying witness refuses to sign the certification contained in Attachment A on the record at the deposition, the witness nevertheless may be shown and questioned about any document (regardless of confidentiality designation) if: (1) it is evident from the document that the witness prepared, received, or reviewed the document prior to its production in this action; (2) the document came from the custodial file of the witness; or (3) the document consists of policies or procedures for the employment responsibilities held by the witness. The use of a document under this provision will not waive the document’s confidentiality designation nor will the witness be entitled to retain a copy of the document. Pages of transcribed deposition testimony or exhibits to depositions that are properly designated as Highly Confidential – Attorneys’ Eyes Only pursuant to the process set out in this Protective Order must be separately bound by the court reporter and may not be disclosed to anyone except permitted under this Protective Order;

- (8) Author or recipient. The author or recipient of the document (not including a person who received the document in the course of litigation); and
- (9) Others by Consent. Other persons only by written consent of the Producing Party or upon order of the Court and on such conditions as may be agreed or ordered.

4. Limited Disclosure for Outside Counsel’s Eyes Only Information

The Parties and counsel for the Parties shall not disclose or permit the disclosure of any Outside Counsel’s Eyes Only Information to any third person or entity except as set forth in

¹ The Parties agree to meet and confer in good faith and as may be necessary, should any issues arise with regard to a particular deposition, relating to the potential advance disclosure of Highly Confidential – Attorneys’ Eyes Only Information intended by a Party to be used in the examination of a witness at that deposition.

subparagraphs (1)-(9). Subject to these requirements, the following categories of persons may be allowed to review Outside Counsel's Eyes Only Information:

- (1) Outside Counsel of record and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel;
- (2) Except as otherwise provided in this Protective Order or any other order in this Litigation, no other employees of any Defendant may receive the Highly Confidential – Outside Counsel's Eyes Only Information of another, or be shown such material at a deposition;
- (3) Mediators, the Court and their personnel;
- (4) Court Reporters and Recorders. Court reporters and recorders engaged for depositions;
- (5) Contractors. Those persons specifically engaged for the limited purpose of making copies of documents or organizing or processing documents, including outside vendors hired to process electronically stored documents, provided that the contractor agrees to be bound by this Protective Order and completes the certification contained in Attachment A;
- (6) Consultants and Experts. Consultants, investigators, or experts employed by the Parties or counsel for the Parties to assist in the preparation and trial of this action but only after such persons have completed the certification in Attachment A;
- (7) Witnesses during deposition who may be shown, but shall not be permitted to retain, Outside Counsel's Eyes Only Information; provided, however, that, unless otherwise agreed by the relevant Parties (whether prior to or at the deposition) or order by the Court, no Outside Counsel's Eyes Only Information of a Defendant may be shown to any witness who is a current employee of another Defendant or is not otherwise authorized to receive the information under this Protective Order.² In the event that a testifying witness refuses to sign the certification contained in Attachment A on the record at the deposition, as required by this Protective Order, the witness nevertheless may be shown and questioned about any

² The Parties agree to meet and confer in good faith and as may be necessary, should any issues arise with regard to a particular deposition, relating to the potential advance disclosure of Highly Confidential – Outside Counsel's Eyes Only Information intended by a Party to be used in the examination of a witness at that deposition.

document (regardless of confidentiality designation) if: (1) it is evident from the document that the witness prepared, received, or reviewed the document prior to its production in this action; (2) the document came from the custodial file of the witness; or (3) the document consists of policies or procedures for the employment responsibilities held by the witness. The use of a document under this provision will not waive the document's confidentiality designation nor will the witness be entitled to retain a copy of the document. Pages of transcribed deposition testimony or exhibits to depositions that are properly designated as Outside Counsel's Eyes Only pursuant to the process set out in this Protective Order must be separately bound by the court reporter and may not be disclosed to anyone except permitted under this Protective Order;

- (8) Author or recipient. The author or recipient of the document (not including a person who received the document in the course of litigation); and
- (9) Others by Consent. Other persons only by written consent of the Producing Party or upon order of the Court and on such conditions as may be agreed or ordered.

5. Open Language Model Limitations

A Receiving Party shall not use or employ any application, service, or analytical software that will transfer, transmit, send, or allow any external access to Confidential Information, Highly Confidential – Attorneys' Eyes Only, or Outside Counsel's Eyes Only Information material (in whole or in part) unless such application, service, or analytical software is fully containerized (i.e., does not transmit any information to any external system or network for the purpose of analysis, use, or the generation of text outputs in response to queries), has the ability to track all information in the system (including access), and does not otherwise allow access to information by unauthorized persons. For the avoidance of doubt, this restriction expressly applies to the use of advanced large language models, "generative" AI tools, and other advanced AI systems, including

but not limited to OpenAI GPT, ChatGPT3/4 et seq., Google Bard, Google Translate, Meta LLAMA, MidJourney, DALL-E, and Stable Diffusion.

6. Control of Documents

Counsel for the Parties shall make reasonable efforts to prevent unauthorized or inadvertent disclosure of Confidential Information, Highly Confidential – Attorneys' Eyes Only, or Outside Counsel's Eyes Only Information. Counsel shall maintain the forms signed by persons acknowledging their obligations under this Protective Order for a period of three years after the termination of the case.

D. Inadvertent Failure to Designate

An inadvertent failure to designate a document as Confidential Information, Highly Confidential – Attorneys' Eyes Only, or Outside Counsel's Eyes Only Information does not, standing alone, waive the right to so designate the document; provided, however, that a failure to serve a timely Notice of Designation of deposition testimony as required by this Protective Order, even if inadvertent, waives any protection for deposition testimony.

If a party designates a document as Confidential Information, Highly Confidential – Attorneys' Eyes Only, or Outside Counsel's Eyes Only Information after it was initially produced, the Receiving Party, on notification of the designation, must make a reasonable effort to assure that the document is treated in accordance with the provisions of this Protective Order.

No Party shall be found to have violated this Protective Order for failing to maintain the confidentiality of material during a time when that material has not been designated Confidential Information, Highly Confidential – Attorneys' Eyes Only, or Outside Counsel's Eyes Only Information, even where the failure to so designate was inadvertent and where the material is

subsequently designated Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information.

E. Filing of Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information

This Protective Order does not, by itself, authorize the filing of any document under seal.

Any party wishing to file a document designated as Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information in connection with a motion, brief or other submission to the Court must comply with the Local Rules of the Eastern District of New York, the Individual Practices of Judge Brian M. Cogan, and Second Circuit case law.

F. No Greater Protection of Specific Documents

Except on privilege grounds (addressed in the Parties’ Privilege Order), no party may withhold information from discovery on the ground that it requires protection greater than that afforded by this Protective Order unless the party moves for an order providing such special protection.

G. Challenges to Confidentiality Designation

The designation of any material or document as Confidential Information, Highly Confidential, and/or Highly Confidential – Attorneys’ Eyes Only is subject to challenge by any Party. The following procedure shall apply to any such challenge.

A Party challenging the designation of Confidential Information, Highly Confidential, or Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information must do so in good faith and must begin the process by conferring directly with counsel for the Producing Party. In conferring, the challenging party must explain the basis for its belief that the

confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the designation, and, if no change in designation is offered, to explain the basis for the designation. The Producing Party must respond in good faith to the challenge within seven (7) calendar days. Failure to respond timely will be presumed to terminate the meet and confer process. Within seven (7) calendar days of the Producing Party's response, the parties shall meet and confer to attempt to resolve the challenge.

If the dispute as to the confidentiality designation cannot be resolved, the parties must, in compliance with Local Rule 37.3 and the Individual Practices of Judge Brian M. Cogan, submit one joint letter to the Court describing the nature of the dispute, identifying the challenged material, and attaching relevant materials. The joint letter shall not exceed three pages in length. Separate and successive letters will not be reviewed by the Court. The joint letter shall include a description of the parties' compliance with meet and confer requirements including the time, place, and duration of the meet and confer, and naming the counsel involved in the discussion. The burden of persuasion in any such challenge proceeding shall be on the Producing Party. Until the Court rules on the challenge, all parties shall continue to treat the materials as Confidential Information, Highly Confidential – Attorneys' Eyes Only, and Outside Counsel's Eyes Only Information under the terms of this Protective Order.

Nothing in this Protective Order or any action or agreement of a party under this Protective Order limits the Court's power to make orders concerning the disclosure of documents produced in discovery or at trial.

H. Use of Confidential Documents or Information at Trial

Nothing in this Protective Order shall be construed to affect the use of any document, material, or information at any trial or hearing. A party that intends to present or that anticipates

that another party may present Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information at a hearing or trial shall bring that issue to the Court’s and parties’ attention by motion or in a pretrial memorandum without disclosing the Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information. The Court may thereafter make such orders as are necessary to govern the use of such documents or information at trial.

The Parties agree to meet and confer in good faith with any Producing Party at least sixty (60) calendar days in advance of any trial in these actions to discuss a stipulation to govern the potential use of any Highly Confidential – Attorneys’ Eyes Only or Outside Counsel’s Eyes Only Information at trial.

I. Confidential Information Subpoenaed or Ordered Produced in Other Litigation

If a Receiving Party is served with a subpoena or an order issued in other litigation (a “Demand”) that would compel disclosure of any material or document designated in this action as Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information, the Receiving Party must so notify the Producing Party, in writing, immediately and in no event more than three (3) business days after receiving the subpoena or order. Such notification must include a copy of the subpoena or court order.

The Receiving Party also must immediately inform in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is the subject of this Protective Order. In addition, the Receiving Party must deliver a copy of this Protective Order promptly to the party in the other action that caused the subpoena to issue.

At the request of the Party or Non-Party who produced or designated the material as

Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information, the Receiving Party shall not comply with the Demand unless (a) ordered to do so by a court with jurisdiction over the Receiving Party; or (b) released in writing by the Party or Non-Party who designated the material as Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information. The burden of opposing the enforcement of the Demand shall fall upon the Producing Party or Non-Party who produced or designated the material as Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information.

The purpose of imposing these duties is to alert the interested persons to the existence of this Protective Order and to afford the Producing Party in this case an opportunity to try to protect its Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information in the court from which the subpoena or order issued. The Producing Party shall bear the burden and the expense of seeking protection in that court of its Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information, and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party in this action to disobey a lawful directive from another court. The obligations set forth in this paragraph remain in effect while the Party has in its possession, custody or control Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and Outside Counsel’s Eyes Only Information produced by the other party.

J. Challenges by Members of the Public to Sealing Orders

A Party or interested member of the public has a right to challenge the sealing of particular documents that have been filed under seal, and the party asserting confidentiality will have the burden of demonstrating the propriety of filing under seal.

K. Obligations on Conclusion of Litigation

Unless otherwise agreed or ordered, this Protective Order shall remain in force after dismissal or entry of final judgment not subject to further appeal.

Within sixty (60) days after dismissal or entry of final judgment not subject to further appeal, all Confidential Information and documents and/or Highly Confidential – Attorneys Eyes Only Information and documents marked “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY,” or “OUTSIDE COUNSEL EYES ONLY” under this Protective Order, including copies as defined in ¶ (III)(A)(4), shall be returned to the Producing Party unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the parties agree to destruction to the extent practicable in lieu of return;³ or (3) as to documents bearing the notations, summations, or other mental impressions of the Receiving Party, that party elects to destroy the documents and certifies to the Producing Party that it has done so.

Retention of Work Product and One Set of Filed Documents. Notwithstanding the above requirements to return or destroy documents, counsel may retain (1) attorney work product, including an index that refers or relates to designated Confidential Information so long as that work product does not duplicate verbatim substantial portions of Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and/or Outside Counsel’s Eyes Only Information, and (2) one complete set of all documents filed with the Court including those filed under seal. Any retained Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and/or Outside Counsel’s Eyes Only Information shall continue to be protected under this Protective Order. An

³ The Parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate, and return e-mails (including attachments to e-mails) that may include Confidential Information, or Confidential Information contained in deposition transcripts or drafts or final expert reports.

attorney may use his or her work product in subsequent litigation, provided that its use does not disclose or use Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and/or Outside Counsel’s Eyes Only Information.

Deletion of Documents Filed under Seal from Electronic Case Filing (ECF) System. Filings under seal shall be deleted from the ECF system only upon order of the Court.

L. Duties in the Event of Unauthorized Disclosures

It shall be the obligation of counsel, upon learning of any unauthorized disclosure or threatened unauthorized disclosure of Confidential Information, or any other breach or threatened breach of the provisions of this Order, to promptly notify counsel for the Producing Party. The notification shall be supplemented with reasonable details of the circumstances of the disclosure in order to permit the Producing Party to understand and take appropriate steps. Each Party and its counsel agree to take reasonable and good-faith efforts to contain or limit any breach promptly upon receiving notice of it, and to make reasonable and good-faith attempts to retrieve any unauthorized disclosure of documents or information.

M. Data Security

The Parties agree to provide adequate security to protect data produced by the other Party(ies) or by Non-Parties. This includes secure data storage systems, established security policies, and security training for employees, contractors and experts. Adequate security also includes such measures as data encryption in transit, data encryption at rest, data access controls, and physical security, whether hosted/outsourced to a vendor or on premises. At a minimum, any Receiving Party subject to the terms of this Confidentiality Order, will provide reasonable measures to protect non-client data consistent with the American Bar Association Standing Committee on Ethics and Professional Responsibility, Formal Opinion 477R.

N. Protective Order Subject to Modification

This Protective Order shall be subject to modification by the Court on its own initiative or on motion of a Party or any other person with standing concerning the subject matter.

O. No Prior Judicial Determination

This Protective Order is entered based on the representations and agreements of the Parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any document or material designated Confidential Information, Highly Confidential – Attorneys’ Eyes Only, and/or Outside Counsel’s Eyes Only Information by counsel or the Parties is entitled to protection under Rule 26(c) of the Federal Rules of Civil Procedure or otherwise until such time as the Court may rule on a specific document or issue.

P. Right To Use Own Material

Nothing in this Protective Order is intended to nor shall modify any Party’s right use its own Protected Material in any manner.

IT IS SO ORDERED.

Dated: Brooklyn, NY
August 1, 2024

Brian M. Cogan

USDJ
[COURT SIGNATURE BLOCK]

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X

IN RE: ORAL PHENYLEPHRINE MARKETING :
AND SALES PRACTICES LITIGATION :
: 23-md-3089-BMC
THIS DOCUMENT APPLIES TO: :
: ALL CASES :
: X

ATTACHMENT A TO QUALIFIED PROTECTIVE ORDER AND AGREED

CONFIDENTIALITY ORDER:

ATTESTATION

I, _____, hereby attest to my understanding that information or documents designated Confidential Information or Highly Confidential Information are provided to me subject to the Confidentiality Order (“Order”) dated _____, entered by the Court in the above-captioned litigation (“Litigation”); that I have been given a copy of and have read the Order; and that I agree to be bound by its terms. I also understand that my execution of this Attestation to the Confidentiality Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any information or documents designated as Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information pursuant to the Order.

I further agree that I shall not disclose to others, except in accord with the Order,

any Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information, in any form whatsoever, and that such Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information and the information contained therein may be used only for the purposes authorized by the Order.

I further agree to return all copies of any documents or information containing Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information I have received to counsel who provided them to me upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Confidential Information, Highly Confidential – Attorneys’ Eyes Only, or Outside Counsel’s Eyes Only Information material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Eastern District of New York, for the purposes of any proceedings relating to enforcement of the Order, even if such enforcement proceedings occur after termination of this action. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Attestation.

Date: _____

Printed Name: _____

Signature: _____